DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

9117d

APR 23 2001

Warning Letter

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

President, CEO
HealthCrest
P.O. Box 1822
Fair Oaks, California 95628

Dear Sir/Madame:

We are writing to you because the Food and Drug Administration (FDA) has received information that revealed a serious regulatory problem with the product labeled "HealthCrest Fertility Awareness kit" which is advertised and sold by your firm.

The device is marketed as a fertility awareness kit that contains a device referred to as "the Lens", an Instruction Booklet, a HealthCrest Warranty, a booklet entitled A Cooperative Method of Natural Birth Control by Margaret Nofzinger, a Fertility Awareness Book, a 11" x 14" Tracking Chart, and a Pocket size Tracking Chart. The promotional brochure for this kit states that the Lens is a fertility awareness tool that allows women to become their own fertility experts, ...A wonderfully reliable, reusable product from Europe that gives the latest medical information... for pinpointing ovulation."

This product is considered to be a medical device under section 201(h) (2) of the Federal Food, Drug, and Cosmetic Act (the Act). A medical device is defined as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, which is intended for use in the diagnosis of disease or other conditions, or in cure, mitigation, treatment, or prevention of disease, in man or other animals or intended to affect the structure or any function of the body of man or other animals. Under this Act, manufacturers, distributors of medical devices are required to obtain marketing clearance (premarket notification) for their product from the FDA before they may offer it for sale.

Our records do not show that you have obtained marketing clearance before you began offering your product for sale. Because you do not have marketing clearance from the FDA, marketing your product is a violation of the law. In legal terms, the product is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your product is adulterated under the Act because you did not submit information that shows your device is safe and effective. Your product is misbranded under the Act because you did not submit information that shows your device is substantially equivalent to other similar devices that are legally marketed. You may obtain FDA's requirements on the type of information to be included in a premarket notification for this device by contacting Dr. Jean Cooper, Chief, Clinical Chemistry and Toxicology Branch, Division of Clinical Laboratory Devices, at 301-594-1243 extension 153. Please note that a guidance document outlining data and labeling requirements for these devices can be found at http://www.fda.gov/cdrh/ode/odec1272.html.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties.

It is necessary for you to take action on this matter now. Please let this office know, in writing, within fifteen (15) working days from the date that you receive this letter what steps your are taking to correct the problem involving the sale of unapproved/uncleared products by your company. We also ask that you explain how you plan to prevent this from happening again and what you will do about unapproved/uncleared products currently in retail outlets. If you need more time, please let us know why and when you expect to complete your correction. Please direct your response to Betty Collins, Chief, In Vitro Diagnostic Devices Branch, Center for Devices and Radiological Health, 2094 Gaither Road, HFZ-321, Rockville, Maryland 20850.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of

medical devices. This letter pertains only to the issue of premarket clearance for your device and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041, or the Internet at http://www.fda.gov.

If you have more specific questions about how FDA marketing affects your particular device, or about the content of the letter, please feel free to contact Dr. A. Gonzalez-Licea at (301) 594-4595 ext. 171.

Sincerely yours,

Larry D. Spears
Acting Director
Office of Compliance
Center For Devices and
Radiological Health

Attachment

Purged 04/24/01

Prepared:AGonzalez
Reviewed:BCollins
Final:jap 9/14/00; 4/18/01
Revised: JRKirk 4/19/01
Final: dr 4/20/01

JRK 4/20/01

Cc:
HFA-224
HFZ-321
HFZ-320
HFZ-306 (2, 1 purged cc to Silver & 1 to Branch)
HFI-35 (Purged)
Track # 84950